IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ELIZABETH HUTCHINSON and JOHN F	1
HUTCHINSON, JR.,	

Plaintiffs,

v.

No. 20-cv-1084-RGA

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION

Robert Joseph Leoni, SHELSBY & LEONI, PA, Stanton, DE; Aaron L. Dunbar, Christopher A. Gomez, Lee B. Balefsky, KLINE & SPECTER, PC, Philadelphia, PA.

Attorneys for Plaintiffs.

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Attorneys for Defendants.

September 25, 2020

/s/ Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Before the Court is Defendant's motion for summary judgment. (D.I. 20). Plaintiffs have submitted an opposition to Defendant's motion. (D.I. 21, 22). I have reviewed the parties' briefing. (D.I. 20, 21, 22).

I. BACKGROUND

Defendant Boston Scientific Corporation moves for summary judgment on the basis that Plaintiffs' claims are barred by Delaware's two-year statute of limitations for personal injury claims. (D.I. 20 at 1). Both sides agree that the dispute is governed by Delaware law. (*Id.* at 4; D.I. 22 at 2).

Defendant's motion lays out twelve material facts. (D.I. 20 at 2-3). Plaintiff¹ agrees with them and adds two additional ones. (D.I. 22 at 1). On November 21, 2008, Plaintiff underwent a procedure in which Avaulta, polypropylene mesh manufactured by Boston Scientific Corporation, was placed to treat her Pelvic Organ Prolapse. (D.I. 20 at 2). Plaintiff began experiencing problems with her Avaulta implant within two weeks of the 2008 surgery, and the problems continued into 2009. (*Id.*). The complained-of medical issues included pain, infection, vaginal scarring, erosion, dyspareunia, and bleeding during sex. (*Id.*).

On April 6, 2009, Plaintiff had a revision surgery due to mesh erosion. (*Id.* at 3). Plaintiff underwent a second revision surgery on July 16, 2009 to remove vaginal scar tissue. (*Id.*). Throughout 2009, Plaintiff continued to suffer from pain, infection, dyspareunia, erosion, and vaginal scarring. (*Id.*). Plaintiff underwent surgery in December 2011 to have the mesh removed. (D.I. 20, Exh. C at 10-11 of 12). During the time from the second revision surgery, in July 2009,

¹ "Plaintiff" in the singular refers to Elizabeth Hutchinson, as John F. Hutchinson, Jr.'s claims are dependent on Elizabeth's claims.

to the mesh removal surgery, in December 2011, Plaintiff continued to experience painful intercourse. (*Id.*).

In May 2012, Plaintiff allegedly saw a television commercial describing transvaginal mesh products as defective.² According to Plaintiff, this time was the first time that she attributed her injuries to the pelvic mesh. (D.I. 21, Exh. A at 10 of 31). Plaintiff filed the complaint in this action on February 22, 2013. (D.I. 1).

Defendant filed a Motion for Summary Judgment asserting that Plaintiff's claims are time-barred by Delaware's two-year statute of limitations for personal injuries. Defendant asserts that Plaintiff knew or should have known that the mesh was the cause of all her symptoms when she was informed of erosion two weeks after surgery and when she underwent two revision surgeries in 2009. (D.I. 20 at 5-6). Defendant argues that because Plaintiff discovered her injuries as early as the first revision surgery (April 6, 2009), and no later than the date of the second revision surgery (July 16, 2009), but did not file suit until February 22, 2013, the Delaware statute of limitations bars Plaintiff's claims. (*Id.*).

Plaintiff argues that Plaintiff's claims are not time barred, as the time of discovery rule tolled the running of the statute of limitations until May 2012 when Plaintiff first saw a television commercial describing transvaginal mesh products as defective. (D.I. 22 at 3). According to Plaintiff, this was the first time that she was informed that a defect of the mesh was the cause of her injuries. (*Id.*). Under Plaintiff's interpretation of the time of discovery rule, the injury was not

² While Plaintiff's Memorandum in Opposition makes this statement (D.I. 22 at 1), there is no evidence in the record that supports it.

discovered until May 2012, meaning that the filing of the complaint on February 22, 2013 was within the statute of limitations.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute" FED. R. CIV. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable

inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247–49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. ANALYSIS

Delaware has a two-year statute of limitations for personal injury claims. *See* Del. Code Ann. tit. 10, § 8119 (West 2020). Section 8119 provides, "No action for recovery of damages upon a claim for alleged personal injuries shall be brought after the expiration of 2 years from the date upon which it is claimed that such alleged injuries were sustained." *Id*.

In the seminal case *Layton v. Allen*, the Delaware Supreme Court set forth the time of discovery rule. *Layton v. Allen*, 245 A.2d 794, 798 (Del. 1968). The court held that where there is an "inherently unknowable injury" suffered by "one blamelessly ignorant of the act or omission and the injury complained of," an injury is sustained under Section 8119 when the "harmful effect first manifests itself and becomes physically ascertainable." *Id.* In application, the statute of limitations begins to run "on the date that 'the alleged negligence first manifests itself and becomes physically ascertainable." *Morton v. Sky Nails*, 884 A.2d 480, 481 (Del. 2005) (quoting *Greco v. University of Delaware*, 619 A.2d 900, 906 (Del. 1993), *overruled on other grounds by Verrastro v. Bayhospitalists*, *LLC*, 208 A.3d 720 (Del. 2019)); *see also Collins v. Wilmington Med. Center*, *Inc.*, 319 A.2d 107, 108 (Del. 1974) ("The statute starts, rather, when a harmful effect first manifests itself and becomes physically ascertainable. In short, manifestation of the problem, not its cure, is the test under *Layton*.").

In other words, the statute begins to run at the time that "the plaintiff is on notice that he or she has sustained a tortious injury." *Brown v. E.I. du Pont de Nemours & Co.*, 820 A.2d 362, 366 (Del. 2003). In *Brown*, the court noted that the statute of limitations period does not start to run "immediately upon the onset of physical problems if the symptoms are reasonably attributable to another cause and the plaintiff is not on notice of the tortious cause." *Id.* at 368. The court ultimately held that the statute of limitations began to run once the plaintiffs "were first on notice of a possible connection between" the injuries and the alleged defective product. *Id.* at 366. Even if there is no actual notice of a potential tort claim, a plaintiff is on inquiry notice when he or she is "chargeable with knowing that his or her rights have been violated." *Id.* at 368 n. 21; *see also Krug v. Beebe Med. Center*, 2003 WL 2241077, at *1 (Del. Super. Ct. Sept. 30, 2003).

Inquiry notice is sufficient to prove, in a summary judgment motion, that the statute of limitations was not tolled. *Smith v. Whelan*, 2013 WL 3169373, at *2 (D. Del. June 21, 2013) (citing *Eluv Holdings (BVI) Ltd. v. Dotomi, LLC*, 2013 WL 1200273, at *6 (Del. Ch. Mar. 26, 2013)), *aff'd*, 556 F. App'x 177 (3d Cir. 2014); *see also Brown*, 820 A.2d at 368 (The "limitations period does not begin to run until the plaintiffs were on notice that the injury may be tortiously caused by the defendant's product.").

In applying the time of discovery rule, the court "must conduct a fact-intensive inquiry to determine whether a plaintiff was blamelessly ignorant of a potential claim or dilatory in pursuing the action." *Brown*, 820 A.2d at 368. Summary judgment in favor of the defendant may be granted when the facts, viewed in the light most favorable to the plaintiff, "predominate toward the conclusion that the plaintiff is chargeable with knowledge that his harmful physical

condition was attributable" to the defendant's product. *Id.* at 366 (quoting *In re Asbestos Litig.*, 673 A.2d 159, 163 (Del. 1996)).

In this case, Plaintiff's harm first manifested itself and became physically ascertainable two weeks after Plaintiff's implantation of Avaulta in November 2008. At her first follow-up appointment, which Plaintiff estimated to be about two weeks after her implantation surgery, Plaintiff's doctor informed her that there was erosion and that it was a problem. (D.I. 20, Exh. C at 5 of 12). Plaintiff had two revision surgeries in 2009, and continued to experience symptoms including pain, infection, dyspareunia, erosion, and vaginal scarring throughout that year.

While such harm might have initially been "inherently unknowable" and Plaintiff might have been "blamelessly ignorant," she was put on notice of the harm when she experienced the complained-of symptoms in 2008 and 2009. The harm was manifested and physically ascertainable, putting her on notice that she had sustained a tortious injury.

This conclusion follows the principles illustrated in the Delaware Supreme Court's decisions in *Morton v. Sky Nails* and *Greco v. University of Delaware*. In *Morton*, the court held that the plaintiff satisfied the "inherently unknowable injury" and "blamelessly ignorant plaintiff" standard until her injury, a rash, appeared. *Morton*, 884 A.2d at 481. After her rash became physically ascertainable, the statute of limitations for her personal injury claim began to run. *Id.* Similarly, in *Greco*, the court held that the plaintiff's personal injury had manifested and was physically ascertainable when she reported her symptoms to a doctor, if not before. *Greco*, 619 A.2d at 906. In this case, Plaintiff did not have an inherently unknowable injury, as she experienced pain and other symptoms, and was not blamelessly ignorant in July 2009, when she underwent a second revision procedure.

While Plaintiff alleges, and the Court takes as true, that no doctor told her that the cause of her injuries was a defect in the pelvic mesh (D.I. 22 at 1), actual notice is not required for the statute of limitations to begin to run. Inquiry notice is sufficient. *See Brown*, 820 A.2d at 368. After being informed of the erosion in 2008 and having two revision surgeries in 2009, it follows that Plaintiff was chargeable with the knowledge that her injuries may be attributable to the polypropylene mesh. At that point, Plaintiff was "chargeable with knowing that…her rights had been violated." *Id*.

This is a situation, unlike *Brown*, where the statute of limitations period began to run immediately after the onset of physical symptoms. Plaintiff's symptoms were not "reasonably attributable to another cause" and Plaintiff was "on notice of the tortious cause." *Id.* In *Brown*, the connection between the injuries (birth defects) and their tortious cause (exposure to a chemical) was not known at the onset of physical symptoms. *Id.* at 365. There were other reasonable causes for the birth defects and the connection to the chemical exposure came later when an expert in the scientific community linked the two. *Id.* The court held that the statute of limitations began to run when the expert made this discovery, putting plaintiffs on notice, for the first time, that their rights had been violated. *Id.* at 368.

Unlike in *Brown*, Plaintiff had no other reasonably attributable cause for her injuries. She began experiencing symptoms soon after the implantation of the mesh and had to have two revision surgeries. (D.I. 20, Exh. C at 5-7 of 12). Further, in Plaintiff's case, at the time of her implantation procedure and revision surgeries, there was a known connection between pelvic mesh implants and the type of injuries Plaintiff suffered.³ At that point, Plaintiff was chargeable

³ The Court has taken judicial notice of the fact that at the time of Plaintiff's implantation procedure and revision surgeries, there was a known connection between pelvic mesh implants and the types of injuries that Plaintiff claims to have suffered. (D.I. 40). There is no reasonable dispute about the existence of this connection in 2008. *See* U.S. FOOD & DRUG ADMIN., FDA PUBLIC HEALTH NOTIFICATION: SERIOUS

with knowing that her rights had been violated, notwithstanding that there is no evidence that she was then following public health notifications or otherwise actually knew about the connection.

She was on inquiry notice of her injuries and their potential connection to the pelvic mesh.

This approach is consistent with the Delaware Superior Court's interpretation of *Brown*. *See Evans v. Genentech, Inc.*, 2015 WL 310248, at *2 (Del. Sup. Ct. Jan. 23, 2015); *Burrell v. Astrazeneca, L.P.*, 2010 WL 3706584, at *5 (Del. Sup. Ct. Sept. 20, 2010). In both cases, the Delaware Superior Court determined that the statute of limitations did not toll where the plaintiffs experienced physical manifestations of their injuries and where the medical community recognized a connection between the product and the injuries. *Evans*, 2015 WL 310248, at *2; *Burrell*, 2010 WL 3706584, at *5-6. The statute of limitations began to run when plaintiffs had ascertainable physical injuries and where plaintiffs were on notice that the product might be the cause. *Evans*, 2015 WL 310248, at *2; *Burrell*, 2010 WL 3706584, at *6.

Plaintiff knew that she had sustained a tortious injury and was on inquiry notice when she experienced injuries, known to be connected to pelvic mesh, after the implantation surgery. The date at which Plaintiff became subjectively aware of the source of her injury is of no consequence, as inquiry notice is sufficient to start the running of the statute of limitations. *See Smith*, 566 F. App'x at 179-80.

No reasonable juror would find that Plaintiff was not on inquiry notice of her injuries and their connection to the pelvic mesh after she experienced erosion two weeks after surgery in 2008, had two revision surgeries in 2009, and there was contemporaneous documentation of

COMPLICATIONS ASSOCIATED WITH TRANSVAGINAL PLACEMENT OF SURGICAL MESH IN REPAIR OF PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE (Oct. 20, 2008), http://wayback.archive-

 $[\]frac{it.org/7993/20170111190506/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm.\\$

implanted pelvic mesh causing such injuries. For that reason, the statute of limitations for Plaintiff's injuries began running in 2009, and the filing of Plaintiff's complaint in 2013 lies outside the two-year statute of limitations.⁴

IV. CONCLUSION

There is no genuine issue of material fact as to when Plaintiff had reason to know of her injury in connection with the polypropylene mesh. The injury was ascertainable, and Plaintiff was on inquiry notice by at least July 2009, the date of Plaintiff's second revision surgery, if not prior. Defendant is entitled to summary judgment on Plaintiffs' claims against it, as the claims are time-barred.

⁴ Under Plaintiff's theory, the statute of limitations would be tolled indefinitely so long as Plaintiff did not pay attention to advertising on television.